



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,727	10/28/2003	Rush E. Simonson	080083.00004	6338
20350	7590	04/24/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			ARAJ, MICHAEL J	
		ART UNIT	PAPER NUMBER	
			3733	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	SIMONSON, RUSH E.
Examiner Michael J. Araj	Art Unit 3733

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 1/30/2006

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 21-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 21-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Claim Status

Claims 21-30 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21,22, 26-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bullivant (U.S. Patent No. 5,507,816) in view of Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3).

Bullivant et al. discloses a surgical method for replacing damaged fibrocartilage in the vertebrae anteriorly where the damage fibrocartilage is removed to create an intervertebral space. Superior and inferior support plates (10 and 14) are inserted into the intervertebral space with the guide of a channel (Col. 4, lines 11-16) and a cushioning member (12) is placed between them to replace the fibrocartilage and absorb forces applied to the intervertebral space. Bullivant et al. discloses the claimed method except for accessing the vertebrae posteriorly. Peckett et al. teaches that spinal surgery is best performed through a posterior approach (page 217, lines 1-2). It is disclosed that a disadvantage of the anterior approach as opposed to the posterior

approach is the potential for visceral or vascular damage (page 216, lines 38-40). Therefore, it would have been obvious to one skilled in the art at the time the method was created to access the vertebrae posteriorly in view of Peckett et al., in order to provide and intervertebral disc endoprosthesis adapted to be inserted posteriorly, achieve long wear life, eliminate posterior spinal pathology and eliminate the need for facet joints.

Claim 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bullivant (U.S. Patent No. 5,507,816) in view of Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3) as applied to claim 21 above, and further in view of Wong et al. ("Paired cylindrical Interbody Cage Fit and Facetectomy...", SPINE Vol. 26, number 5).

The combination of Bullivant in view of Peckett et al., as applied to claim 21, discloses the claimed invention except performing a partial discectomy that includes removing the adjacent facets that would allow posterior access of the superior and inferior vertebrae at the desired site location of the implant. Wong et al. teaches a facetectomy to give access to the implant location. They also teach that hemi-facetectomy are preferred because near-total or total removal of the facets could significantly compromise vertebral stability and successful interbody fusion. (Page 575, Col. 2, lines 16-22) It would have been obvious to one skilled in the art at the time the invention was made to develop the method with the combination of Bullivant as modified by Peckett et al. to only remove the spinous process and the inferior articular process of

the superior vertebrae and the superior articular process of the inferior vertebrae in view of Wong et al.

Claims 23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bullivant (U.S. Patent No. 5,507,816) as modified by Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3) Wong et al. ("Paired cylindrical Interbody Cage Fit and Facetectomy...", SPINE Vol. 26, number 5), as applied to claim 11 above, and further in view of Beer et al. (U.S. Patent No. 5,458,642).

The combination of Bullivant, Peckett et al. and Wong et al. discloses the claimed method except for the cushioning member being a coil spring. Beer et al. discloses a coil spring (13) to act as a cushioning member in the vertebral implant. It would have been obvious to one skilled in the art at the time the invention was made to develop the method with the combination of Bullivant as modified by Peckett et al. and Wong et al., to have the cushioning member be a coil spring in view of Beer et al. because the coil spring distributes forces acting on the disc between the springs and allows for normal movement of the vertebrae.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bullivant (U.S. Patent No. 5,507,816) as modified by Peckett et al. ("the Hartshill Horseshoe: Journal of Musculoskeletal Research Vol. 4. No. 3) and Wong et al. ("Paired cylindrical Interbody Cage Fit and Facetectomy...", SPINE Vol. 26, number 5), as applied to claim 21 above, and further in view of Gauchet et al. (U.S. Patent No. 6,579,320).

The combination of Bullivant, Peckett et al. and Wong et al. discloses the claimed method except for the cushioning member being a dampening matrix comprising a hydrogel core positioned within a constraining jacket. Gauchet et al. discloses a hydrogel core (16) dampening matrix positioned within a constraining jacket (26) to act as a cushioning member in the vertebral implant. It would have been obvious to one skilled in the art at the time the invention was made to develop the method with the combination of Bullivant as modified by Peckett et al. and Wong et al., to have the cushioning member be a dampening matrix comprising a hydrogel core positioned within a constraining jacket in view of Gauchet et al. because this allows the prosthesis to imitate the mechanical properties of a healthy natural intervertebral disk.

Response to Arguments

Applicant's arguments filed January 30, 2006 have been fully considered but they are not persuasive. The art disclosed in this action have the proper and appropriate motivation to have made this invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PEDRO PHILOGENE
PRIMARY EXAMINER